AMENDED IN ASSEMBLY APRIL 22, 2009

CALIFORNIA LEGISLATURE—2009–10 REGULAR SESSION

ASSEMBLY BILL No. 542

Introduced by Assembly Member Feuer

February 25, 2009

An act to amend Sections 1279.1 and 1279.2 of, to add Sections 1279.4 and 1371.6 to, to add and repeal Chapter 2.32 (commencing with Section 1414.10) to Division 2 of, and to add ~~Chapter 4~~ *Part 5.5* (commencing with Section 128870) ~~of Part 5 of~~ *to* Division 107 of, the Health and Safety Code, to add Sections 10191.5, 12693.56, 12699.06, and 12739.5 to the Insurance Code, and to add Article 5.4 (commencing with Section 14182) to Chapter 7 of Part 3 of Division 9 of the Welfare and Institutions Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 542, as amended, Feuer. Adverse medical events.

Existing law establishes various programs for the prevention of disease and the promotion of health, including, but not limited to, the licensing and regulation of health facilities to be administered by the State Department of Public Health. Existing law requires specified health facilities to report patient adverse events to the department within 5 days.

This bill would expand the specified adverse events requiring reporting to include, among others, manifestations of poor glycemic control, catheter-associated urinary tract infection, and surgical-site infection, and would require a surgical clinic to comply with these health facility adverse event reporting requirements. The bill would require the department to collect adverse event information, and investigate adverse events.

This bill would require the medical director or the director of specified facilities to annually report adverse events to its governing board and would require a contract between a health care provider and a health care services plan to be consistent with policies of nonbilling for, and nonpayment of, substantiated adverse events.

This bill would require the State Public Health Officer to establish ~~an Office of Quality Improvement and Reporting~~ *the Office of Patient Safety* within the department to provide leadership in reducing adverse events and improving patient safety and quality of care. The bill would require a health facility or clinic to conduct a root cause analysis of an adverse event and to report to the office and the patient, as prescribed.

~~This bill would require the Secretary of California Health and Human Services to establish a Health Care Quality Improvement Committee for the purpose of developing recommendations for nonbilling and nonpayment policies and practices for substantiated adverse events, and would require the committee to report its initial recommendations by September 1, 2010. The~~

This bill would require the Department of Managed Health Care, in collaboration with the State Department of Public Health, the State Department of Health Care Services, the Managed Risk Medical Insurance Board, the California Public Employees' Retirement System, and the Department of Insurance, to adopt and implement regulations that establish uniform policies and practices governing the nonpayment of health care providers for substantiated adverse events by state public health programs. The bill would require, after the adoption of these regulations, that the State Department of Public Health, the State Department of Health Care Services, the Managed Risk Medical Insurance Board, the California Public Employees' Retirement System, and the Department of Insurance, adopt and implement similar regulations. The bill would prohibit a health care provider from billing for services related to a substantiated adverse event.

Existing law provides for the Healthy Families Program, administered by the Managed Risk Medical Insurance Board, under which health care services are provided to qualified low-income children.

Existing law provides for the Medi-Cal program, administered by the State Department of Health Care Services under which health care services are provided to qualified low-income persons.

This bill would require that contracts between a health care provider and health care service plan, an insurer, the Healthy Families Program, or the Medi-Cal program be consistent with those nonbilling and

nonpayment policies for substantiated adverse events. By changing the definition of existing crimes, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) Patients seeking medical treatment have a right to quality medical care delivered in a timely, safe, and appropriate manner.

(b) Licensed health facilities and health care providers are vital community resources that perform life-saving procedures and ensure the health and welfare of the general public.

(c) Despite the best intentions of health care providers, when an adverse event occurs, a patient can be harmed, potentially leading to serious disability or even death.

(d) Most adverse events can be prevented through ongoing health care provider education and established safety plans and procedures. It is the policy of the State of California to encourage constant monitoring and continuous improvement in health care quality processes to ensure patient safety.

(e) It is the policy of the State of California that patients and purchasers of health care services should not be billed for substantiated adverse events. It is also the policy of the State of California that adverse events, when substantiated, should not be reimbursed by patients or purchasers of health care services.

(f) Patients who have been harmed by an adverse event must receive the medically necessary followup care to correct or treat the complications or consequences of the adverse event, to the extent possible. Medically necessary followup care and services should be reimbursed.

(g) The development of policies and procedures for the nonbilling and nonpayment of adverse events is a complex process

that requires expertise from many sectors of the health care delivery system. While these policies and procedures are being established, the State of California encourages private sector solutions that bring improvement in the delivery of health care services and a reduction in the occurrence of adverse events.

SEC. 2. Section 1279.1 of the Health and Safety Code is amended to read:

1279.1. (a) A health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250 or a surgical clinic licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 shall report an adverse event to the licensing and certification division of the department no later than five days after the adverse event has been detected, or, if that event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, not later than 24 hours after the adverse event has been detected. Disclosure of individually identifiable patient information shall be consistent with applicable law.

(b) For purposes of this section, "adverse event" includes any of the following:

(1) Surgical events, including the following:

(A) Surgery performed on a wrong body part that is inconsistent with the documented informed consent for that patient. A reportable event under this subparagraph does not include a situation requiring prompt action that occurs in the course of surgery or a situation that is so urgent as to preclude obtaining informed consent.

(B) Surgery performed on the wrong patient.

(C) The wrong surgical procedure performed on a patient, which is a surgical procedure performed on a patient that is inconsistent with the documented informed consent for that patient. A reportable event under this subparagraph does not include a situation requiring prompt action that occurs in the course of surgery, or a situation that is so urgent as to preclude the obtaining of informed consent.

(D) Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained.

(E) Death during or up to 24 hours after induction of anesthesia after surgery of a normal, healthy patient who has no organic, physiologic, biochemical, or psychiatric disturbance and for whom

the pathologic processes for which the operation is to be performed are localized and do not entail a systemic disturbance.

(2) Product or device events, including the following:

(A) Patient death or serious disability associated with the use of a contaminated drug, device, or biologic provided by the health facility when the contamination is the result of generally detectable contaminants in the drug, device, or biologic, regardless of the source of the contamination or the product.

(B) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. For purposes of this subparagraph, "device" includes, but is not limited to, a catheter, drain, or other specialized tube, infusion pump, or ventilator.

(C) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a facility, excluding deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

(3) Patient protection events, including the following:

(A) An infant discharged to the wrong person.

(B) Patient death or serious disability associated with patient disappearance for more than four hours, excluding events involving adults who have competency or decisionmaking capacity.

(C) A patient suicide or attempted suicide resulting in serious disability while being cared for in a health facility due to patient actions after admission to the health facility, excluding deaths resulting from self-inflicted injuries that were the reason for admission to the health facility.

(4) Care management events, including the following:

(A) A patient death or serious disability associated with a medication error, including, but not limited to, an error involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose.

(B) A patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.

(C) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a facility, including events that occur within 42 days postdelivery

and excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy.

(D) Patient death or serious disability directly related to manifestations of poor glycemic control, the onset of which occurs while the patient is being cared for in a health facility. For the purposes of this section, "manifestations of poor glycemic control" include, but are not limited to, hypoglycemia, diabetic ketoacidosis, nonketotic hyperosmolar coma, hypoglycemic coma, secondary diabetes with ketoacidosis, or secondary diabetes with hyperosmolarity.

(E) Death or serious disability, including kernicterus, associated with failure to identify and treat hyperbilirubinemia in neonates during the first 28 days of life. For purposes of this subparagraph, "hyperbilirubinemia" means bilirubin levels greater than 30 milligrams per deciliter.

(F) A Stage 3 or 4 ulcer, acquired after admission to a health facility, excluding progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.

(G) A patient death or serious disability due to spinal manipulative therapy performed at the health facility.

(H) Patient death or serious disability due to a catheter-associated urinary tract infection (UTI).

(I) Vascular catheter-associated infection.

(J) Mediastinitis after coronary bypass graft.

(K) Surgical site infection following orthopedic procedures, as defined in subparagraph (O).

(L) Surgical site infection following bariatric surgery for obesity.

(M) Deep vein thrombosis following orthopedic procedures, as defined in subparagraph (O).

(N) Pulmonary embolism following orthopedic procedures, as defined in subparagraph (O).

(O) For the purposes of subparagraphs (K), (M), and (N), "orthopedic procedures" means one or more of the following procedures: atlas-axis fusion, other cervical fusion, dorsal/dorsulum fusion, lumbar/lumbosac fusion, arthrodesis of shoulder, arthrodesis of elbow, refusion of atlas-axis, refusion of cervical spine, refusion of dorsal spine, refusion of lumbar spine, shoulder arthroplast, or elbow arthroplast.

(5) Environmental events, including the following:

(A) A patient death or serious disability associated with an electric shock while being cared for in a health facility, excluding events involving planned treatments, such as electric countershock.

(B) Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by a toxic substance.

(C) A patient death or serious disability associated with a burn incurred from any source while being cared for in a health facility.

(D) A patient death associated with a fall while being cared for in a health facility.

(E) A patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health facility.

(6) Criminal events, including the following:

(A) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider.

(B) The abduction of a patient of any age.

(C) The sexual assault on a patient within or on the grounds of a health facility.

(D) The death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a facility.

(7) An adverse event or series of adverse events that cause the death or serious disability of a patient, personnel, or visitor.

(c) The facility shall inform the patient or the party responsible for the patient of the adverse event by the time the report is made.

(d) "Serious disability" means a physical or mental impairment that substantially limits one or more of the major life activities of an individual, or the loss of bodily function, if the impairment or loss lasts more than seven days or is still present at the time of discharge from an inpatient health care facility, or the loss of a body part.

(e) Nothing in this section shall be interpreted to change or otherwise affect hospital reporting requirements regarding reportable diseases or unusual occurrences, as provided in Section 70737 of Title 22 of the California Code of Regulations. The department shall review Section 70737 of Title 22 of the California Code of Regulations requiring hospitals to report "unusual occurrences" and consider amending the section to enhance the clarity and specificity of this hospital reporting requirement.

(f) (1) Notwithstanding any other provision of law, the licensing and certification division of the department shall collect information regarding substantiated adverse events. The information shall include, but need not be limited to, patient name and payer source, and shall be provided to state government payers, including, but not limited to, the State Department of Health Care Services and the Managed Risk Medical Insurance Board.

(2) State payers shall maintain the confidentiality of the information obtained and only use the information for program administration. The information shall not be disclosed further, except to consultants and contractors with whom the payers share the information for the purposes of program administration, including the purposes of this section and of ~~Chapter 5~~ *Part 5.5* (commencing with Section ~~128872) of Part 5~~ *128870)* of Division 107.

(3) Any costs associated with the compilation and distribution of information gathered pursuant to this subdivision shall be shared on a pro rata basis by the state agencies receiving this information.

SEC. 3. Section 1279.2 of the Health and Safety Code is amended to read:

1279.2. (a) (1) In any case in which the department receives a report from a facility pursuant to Section 1279.1, or a written or oral complaint involving a health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250, that indicates an ongoing threat of imminent danger of death or serious bodily harm, the department shall make an onsite inspection or investigation within 48 hours or two business days, whichever is greater, of the receipt of the report or complaint and shall complete that investigation within 45 days.

(2) Until the department has determined by onsite inspection that the adverse event has been resolved, the department shall, not less than once a year, conduct an unannounced inspection of any health facility that has reported an adverse event pursuant to Section 1279.1.

(b) In any case in which the department is able to determine from the information available to it that there is no threat of imminent danger of death or serious bodily harm to that patient or other patients, the department shall complete an investigation of the report within 45 days.

(c) (1) The department shall notify the complainant and licensee in writing of the department's determination as a result of an inspection or report.

(2) In concluding the investigation of a reported adverse event, the department shall determine whether the adverse event was substantiated or not.

(d) For purposes of this section, "complaint" means any oral or written notice to the department, other than a report from the health facility, of an alleged violation of applicable requirements of state or federal law or an allegation of facts that might constitute a violation of applicable requirements of state or federal law.

(e) The costs of administering and implementing this section shall be paid from funds derived from existing licensing fees paid by general acute care hospitals, acute psychiatric hospitals, and special hospitals.

(f) In enforcing this section and Sections 1279 and 1279.1, the department shall take into account the special circumstances of small and rural hospitals, as defined in Section 124840, in order to protect the quality of patient care in those hospitals.

(g) In preparing the staffing and systems analysis required pursuant to Section 1266, the department shall also report regarding the number and timeliness of investigations of adverse events initiated in response to reports of adverse events.

SEC. 4. Section 1279.4 is added to the Health and Safety Code, to read:

1279.4. (a) The medical director and the director of nursing of each health facility, as defined by subdivision (a), (b), or (f) of Section 1250, shall report annually to the board of directors or other similar governing body the following:

(1) The number of adverse events that occurred in the facility in the most recent 12-month period.

(2) The outcomes for each patient involved.

(3) A comparison to comparable institutions of rates of adverse events, if this data exists and is publicly available.

(b) No communication of data or information pursuant to this section by an officer or employee of the corporation to the governing body shall constitute a waiver of privileges preserved by Section 1156, 1156.1, or 1157 of the Evidence Code or Section 1370.

SEC. 5. Section 1371.6 is added to the Health and Safety Code, to read:

1371.6. (a) A contract between a health care provider and a health care service plan shall be consistent with the adoption, implementation, and exercise of nonpayment and nonbilling policies and practices for substantiated adverse events, as defined by the ~~federal Centers for Medicare and Medicaid Services and the recommendations of the Health Care Quality Improvement Committee as accepted by the Secretary of California Health and Human Services pursuant to Chapter 5 (commencing with Section 128872) of Part 5 of Division 107.~~ *regulations adopted pursuant to Section 128871.*

(b) A health care provider shall not bill a patient for care and services for which payment is denied by a health care service plan pursuant to nonpayment policies and practices for substantiated adverse events pursuant to this section.

(c) The director may require additional documentation from a health care service plan to ensure that any contract authorized under this section shall provide medically necessary care and reimbursement for patients in compliance with this section.

(d) Nothing in this section shall be construed to impair or impede the application of any other provision of this chapter, including, but not limited to, Sections 1367, 1371, 1371.37, and 1375.7.

(e) For the purposes of this section, "health care provider" means any health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250, and a surgical clinic licensed pursuant to paragraph (1) of subdivision (b) of Section 1204.

SEC. 6. Chapter 2.32 (commencing with Section 1414.10) is added to Division 2 of the Health and Safety Code, to read:

Chapter 2.32. Adverse Events

1414.10. For purposes of this chapter, the following definitions apply:

(a) "Department" means the State Department of Public Health.

(b) "Director" means the State Public Health Officer or his or her designee.

(c) "Health care provider" means an individual or entity licensed or certified under state or federal law to provide health care services.

(d) "Health facility" means a health care entity licensed pursuant to subdivision (a), (b), or (f) of Section 1250.

(e) "Office" means the Office of ~~Quality Improvement and Reporting~~ *Patient Safety* established pursuant to Section 1414.15.

(f) "Patient" means a person who receives or should have received health care or treatment from a health facility or clinic.

(g) "Root cause analysis" means a step-by-step method that leads to the discovery of an adverse event's first or primary cause. There is a definite progression of actions and consequences that lead to an adverse event. A root cause analysis investigation traces the cause and effect trail from the end event back to the root cause.

(h) "Patient safety work product" means all data, reports, records, memoranda, analyses, including root cause analyses, and written and oral statements that are assembled or developed by a health care provider and are reported to a quality improvement organization.

(i) "Surgical clinic" means an individual or entity licensed pursuant to paragraph (1) of subdivision (b) of Section 1204.

1414.15. (a) The director shall establish the Office of ~~Quality Improvement and Reporting~~ *Patient Safety* as a distinct program within the State Department of Public Health to provide state leadership in reducing adverse events and ~~improve~~ *improving* patient safety and quality of care.

(b) The office shall establish or utilize a reporting system designed to receive adverse event reports in order to promote patient safety and facilitate quality improvement in the health care system. The reporting system shall consist of mandatory reports from the licensing and certification division of the department of information and data on surgical clinic and health facility submitted reports of adverse events as required by Section 1279.1.

1414.20. (a) Any document or oral statement that constitutes the disclosure provided to a patient or the patient's family member or guardian pursuant to section 1414.30 shall not be used in an adverse employment action.

(b) All information and records, reports, analyses, and corrective action plans obtained or produced in connection with the operation of the office pursuant to this chapter shall be confidential and shall only be used to carry out the duties of the office and shall not be further disclosed. This limitation, however, does not apply to the department's independent investigatory authority with regard to

licensing of health facilities and clinics. In no case shall the information or documents prepared or produced in accordance with this chapter be admissible to prove negligence or culpable conduct.

1414.25. Following the occurrence of an adverse event as described in Section 1279.1, a health facility or a surgical clinic shall conduct a root cause analysis of the event. Following the analysis, the facility or clinic may develop and implement a corrective action plan to address the findings of the analysis. The findings of the root cause analysis and a copy of the corrective action plan must be filed with the office within 60 calendar days of the event. If the facility or clinic conducts an analysis and then chooses not to develop or implement a corrective action plan, it shall report to the office the reasons for not taking corrective action within 60 calendar days of the event.

1414.30. (a) A health facility or surgical clinic shall ensure that the patient affected by an adverse event as described in Section 1279.1, or in the case of a minor or a patient who is incapacitated, the patient's parent or guardian or other family member, as appropriate, is informed of the adverse event by the time the report is made to the department pursuant to subdivision (a) of Section 1279.1.

(b) The time, date, and participants involved in informing the patient of the adverse event shall be documented.

(c) Notification required by subdivision (a) shall not constitute an acknowledgment or admission of liability.

1414.35. (a) The office shall analyze both of the following:

(1) Adverse event reports, corrective action plans, and the root cause analyses submitted to the office pursuant to Section 1414.25.

(2) Patient safety work product submitted by health care providers.

(b) The analysis required under subdivision (a) shall be utilized to identify patterns of systemic failure in the health care system and include successful methods to correct these failures.

(c) The office shall communicate with the health facilities and surgical clinics involved in the adverse event any recommendations for corrective action resulting from the office's analysis required under subdivision (a) so as to stimulate adoption of patient safety practices to improve health care quality.

(d) The office shall establish the means by which to develop, evaluate, and disseminate educational programs and best practices for both providers and the public.

1414.40. The office may, on an annual basis, survey a representative sample of health care facilities, clinics, and the public for the purpose of obtaining information on the effectiveness of the office's activities. The results of the surveys may be utilized to evaluate and modify the office's activities.

1414.45. Moneys collected by the department as a result of administrative penalties imposed under Sections 1280.1 and 1280.3 shall be deposited into the Licensing and Certification Program Fund established pursuant to Section 1266.9. These moneys shall be tracked and available for expenditure, upon appropriation by the Legislature, to support the office as well as additional departmental quality activities.

~~SEC. 7. Chapter 4 (commencing with Section 128870) is added to Part 5 of Division 107 of the Health and Safety Code, to read:~~

~~CHAPTER 4. ADVERSE EVENTS~~

~~128870.~~

SEC. 7. Part 5.5 (commencing with Section 128870) is added to Division 107 of the Health and Safety Code, to read:

PART 5.5. ADVERSE EVENTS

128870. For the purposes of this ~~chapter~~ *part*, the following definitions shall apply:

~~(a) "Adverse event" shall have the same meaning as described in subdivision (b) of Section 1279.1 except that it shall not include events described in paragraph (7) of subdivision (b) of Section 1279.1.~~

~~(b) "Committee" means the Health Care Quality Improvement Committee established pursuant to Section 128871.~~

~~(c)~~

(a) "Health care provider" means a health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250 or a surgical clinic licensed pursuant to paragraph (1) of subdivision (b) of Section 1204.

~~(d)~~

(b) "Patient" means a person who receives or should have received health care or treatment from a health facility or clinic regardless of insurance status or health benefits.

~~(e)~~

(c) "Payer" means all health care insurers, health care service plans, Medi-Cal managed care plans contracting with the State Department of Health Care Services pursuant to Chapter 7 (commencing with Section 14000), Chapter 8 (commencing with Section 14200), or Chapter 8.75 (commencing with Section 14590) of Part 3 of Division 9 of the Welfare and Institutions Code, self-insured employers, and any state or local government entity that pays claims for the provision of health care services by a health care provider.

~~(f)~~

(d) "Serious disability" shall have the same meaning as described in subdivision (d) of Section 1279.1.

~~128871. (a) The Secretary of California Health and Human Services shall establish the Health Care Quality Improvement Committee within a specified department of the California Health and Human Services Agency for the purpose of developing recommendations for nonbilling and nonpayment policies and practices for substantiated adverse events defined in Section 1279.1.~~

~~(b) The committee shall be composed of members appointed as follows:~~

~~(1) The secretary shall appoint:~~

~~(A) Two academic researchers whose experience and focus of study include health care quality and safety.~~

~~(B) One representative with experience in medical payment systems, including claims, billing, and information technology.~~

~~(C) One representative with experience in private hospital financing.~~

~~(D) One representative with experience in public hospital financing.~~

~~(E) One chief nursing officer of a hospital in current practice as a licensed nurse or nurse practitioner licensed in California.~~

~~(F) One representative of health insurers or health care service plans.~~

~~(G) One chief medical officer (CMO) or patient safety officer (PSO) of a hospital in current practice as a patient care physician licensed in California.~~

~~(H) One representative of nonnursing, nonphysician hospital support staff.~~

~~(I) One representative of large employers that purchase group health care coverage for employees and that is not also a supplier or broker of health care coverage.~~

~~(J) One consumer or patient advocate.~~

~~(K) One pharmacist with a hospital leadership role, licensed in California.~~

~~(2) The committee shall also include one representative from each of the following who will participate on the committee in an ex officio, nonvoting capacity:~~

~~(A) State Department of Public Health.~~

~~(B) State Department of Health Care Services.~~

~~(C) Managed Risk Medical Insurance Board (MRMIB).~~

~~(D) California Public Employees Retirement System (CalPERS).~~

~~(E) Department of Managed Health Care.~~

~~(F) Department of Insurance.~~

~~(c) The secretary shall designate the committee chair and cochair. The chair or cochair may be a representative who is an ex officio, nonvoting member of the committee.~~

~~(d) The committee may establish technical or clinical advisory subcommittees as necessary to develop its recommendations.~~

~~(e) The committee shall meet within 90 days of the operative date of this section and shall meet at least every other month.~~

~~(f) (1) Committee recommendations shall include:~~

~~(A) Policies and practices for determining the care or services related to the adverse event that should not be billed or paid.~~

~~(B) Policies and practices for health care providers and payers regarding the presence of adverse events on admission.~~

~~(C) Methodologies to monitor and enforce policies and practices to ensure compliance with nonbilling or nonpayment policies for substantiated adverse events.~~

~~(D) Processes through which health care providers may appeal payments denied pursuant to this chapter for the care and services related to a substantiated adverse event.~~

~~(E) Guidelines for health care providers and payers to distinguish, for each type of adverse event, services and charges~~

~~directly related to the adverse event from those services that constitute medically necessary followup care to correct or treat the complications or consequences of the adverse event or for the care originally sought by the patient.~~

~~(F) Methodologies to synchronize, to the extent feasible, definitions, coding, and practices with the federal Centers for Medicare and Medicaid Services regarding nonbilling and nonpayment policies and practices developed pursuant to the events listed in paragraph (1) of subdivision (g).~~

~~(2) In developing its recommendations, the committee shall review state and national policies and practices of public and private payers and health care providers that have implemented nonbilling and nonpayment policies for adverse events.~~

~~(g) (1) (A) The committee shall make initial recommendations to the Secretary of California Health and Human Services by September 1, 2010. These initial recommendations may be limited to nonpayment and nonbilling policies for substantiated adverse events as defined in all of the following:~~

~~(i) Subparagraphs (A), (B), (C), and (D) of paragraph (1) of subdivision (b) of Section 1279.1.~~

~~(ii) Subparagraph (C) of paragraph (2) of subdivision (b) of Section 1279.1.~~

~~(iii) Subparagraphs (B), (F), (H), (I), and (J) of paragraph (4) of subdivision (b) of Section 1279.1.~~

~~(iv) Subparagraphs (A), (C), and (D) of paragraph (5) of subdivision (b) of Section 1279.1.~~

~~(B) If so limited, the committee shall thereafter recommend nonbilling and nonpayment policies and practices for the remaining adverse events defined under Section 1279.1. Subsequent recommendations shall be provided to the secretary within 12 months of the initial recommendations but no later than October 1, 2011.~~

~~(2) Nothing in this section shall preclude the committee from determining in its recommendations to the secretary that nonbilling and nonpayment policies and practices are not appropriate for a particular adverse event.~~

~~(3) Within 90 days of receipt of committee recommendations, the secretary shall do one of the following:~~

~~(A) Refer the recommendations back to the committee and request additional or modified recommendations in specific areas.~~

~~(B) Advise the committee as to which recommendations will be considered in the development of regulations or other actions to implement this section.~~

~~(C) Adopt the recommendations and seek regulatory or statutory changes or take other actions necessary to implement the approved polices for the nonpayment and/or nonbilling practices for substantiated adverse events.~~

~~(h) Committee and subcommittee members shall serve on a volunteer basis without compensation but shall be reimbursed for necessary expenses incurred in the performance of their committee-specific activities. Reimbursements for such expenses shall be consistent with existing state policies for travel regulations and rates.~~

~~(i) The committee shall provide opportunities for interested consumers, patients, purchasers, and providers to participate in committee meetings.~~

~~(j) The State Department of Health Care Services, the State Department of Public Health, and MRMIB shall share reasonable costs associated with the committee and will provide the necessary administrative and staffing support for the committee activities contingent upon each department receiving an appropriation from the Legislature for that support.~~

~~(k) To the extent appropriate, the State Department of Health Care Services, the State Department of Public Health, and MRMIB will seek federal financial participation to support committee activities.~~

~~(*l*) The secretary may seek partnership with an independent nonprofit group, foundation, or academic institution or governmental entity for purposes of carrying out the necessary activities of the committee.~~

~~(m) This chapter shall be implemented only to the extent funds are appropriated for purposes of this section in the annual Budget Act or in another statute.~~

~~(n) The California Health and Human Services Agency may accept and expend private funds that are received by the agency for the purposes of this section.~~

128871. (a) The Department of Managed Health Care, in collaboration with the State Department of Public Health, the State Department of Health Care Services, the Managed Risk Medical Insurance Board, the California Public Employees'

Retirement System, and the Department of Insurance, shall adopt and implement regulations that establish uniform policies and practices governing the nonpayment of health care providers for substantiated adverse events by state public health programs as follows:

(1) On or before September 1, 2010, adopt payment policies and practices regarding nonpayment for substantiated adverse events that are consistent with those developed by the federal Centers for Medicare and Medicaid Services (CMS) pursuant to Section 5001(c) of the Deficit Reduction Act of 2005 (42 U.S.C. Sec. 1395ww(d)(4)).

(2) Synchronize definitions, coding, and practices, to the extent feasible, with CMS regarding nonpayment for substantiated adverse events.

(3) On or before October 1, 2011, establish a process for identifying and designating additional events as adverse events for purposes of nonpayment policies and practices for state public health programs. These regulations shall include, but not be limited to, one or more criteria or other characteristics of an event that demonstrate that a health care provider should not be permitted to bill or receive payment for the event because it resulted in placing the safety of a patient at risk.

(b) The Department of Managed Health Care, in collaboration with the State Department of Public Health, the State Department of Health Care Services, the Managed Risk Medical Insurance Board, the California Public Employees' Retirement System, and the Department of Insurance, may consult with individuals with relevant clinical and other health care expertise to assist in the development of the regulations adopted pursuant to this section.

(c) After the Department of Managed Health Care has adopted the regulations required pursuant to this section, the State Department of Public Health, the State Department of Health Care Services, the Managed Risk Medical Insurance Board, the California Public Employees' Retirement System, and the Department of Insurance shall adopt regulations that are identical or substantially similar to those regulations adopted pursuant to subdivision (a).

128872. In accordance with the nonbilling and nonpayment policies and practices ~~recommended by the committee and accepted by the Secretary of California Health and Human Services~~ *adopted*

by regulation pursuant to Section 128871, a health care provider shall not bill, nor is a patient or payer required to pay, for substantiated adverse events. When a substantiated adverse event occurs, the health care provider shall disclose the occurrence of the event to the applicable payer.

128873. (a) This ~~chapter~~ *part* shall not be interpreted or implemented in a way that would limit patient access to needed health care services or payment to health care providers for medically necessary followup care to correct or treat the complications or consequences of the adverse event or for the care originally sought by the patient.

(b) For state and local government health care programs that receive federal funds, this ~~chapter~~ *part* shall be implemented only to the extent that federal financial participation for those programs is not jeopardized.

~~128874. This chapter shall become inoperative on July 1, 2013, and, as of January 1, 2004, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2014, deletes or extends the dates on which it becomes inoperative and is repealed.~~

SEC. 8. Section 10191.5 is added to the Insurance Code, to read:

10191.5. (a) A contract between a health care provider and an insurer shall be consistent with the adoption, implementation, and exercise of nonpayment policies and practices for substantiated adverse events as defined by the federal Centers for Medicare and Medicaid Services ~~and the recommendations made by the Health Care Quality Improvement Committee and accepted by the Secretary of California Health and Human Services~~ *regulations adopted* pursuant to Section 128871 of the Health and Safety Code.

(b) Pursuant to this section, a health care provider shall not bill a patient for care and services for which payment is denied by an insurer pursuant to nonpayment policies and practices for substantiated adverse events.

(c) The commissioner may require additional documentation from an insurer to ensure that any contract authorized under this section shall provide medically necessary care and reimbursement for patients in compliance with this section.

(d) For the purposes of this section, "health care provider" means any health facility licensed pursuant to subdivision (a), (b), or (f)

of Section 1250 of the Health and Safety Code, and a surgical clinic licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code.

SEC. 9. Section 12693.56 is added to the Insurance Code, to read:

12693.56. (a) For the purposes of this section, "health care provider" means a health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250 of the Health and Safety Code, and a surgical clinic licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code.

(b) The board shall implement nonbilling or nonpayment policies and practices, alone or in combination, consistent with the ~~recommendations made by the Health Care Quality Improvement Committee and accepted by the Secretary of California Health and Human Services~~ *regulations adopted* pursuant to Section 128871 of the Health and Safety Code, for the program. This subdivision shall be implemented only if, and to the extent that, federal financial participation is available and is not jeopardized.

(c) A health care provider shall not bill a patient for care and services for which payment is denied by the program, including its participating health, dental, and vision plans.

(d) The board may contract with a review organization that meets all applicable state and federal requirements, including Sections 1320c-1 and 1320c-3 of Title 42 of the United States Code, in terms of composition and function, for the purposes of carrying out the ~~recommendations of the Health Care Quality Improvement Committee and accepted by the Secretary of California Health and Human Services~~ *regulations adopted* pursuant to Section 128871 of the Health and Safety Code, for the Healthy Families Program and to the extent feasible, for all other programs administered by the board.

SEC. 10. Section 12699.06 is added to the Insurance Code, to read:

12699.06. (a) For the purposes of this part, "health care provider" means a health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250 of the Health and Safety Code, and a surgical clinic licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code.

(b) The board shall implement nonbilling or nonpayment policies and practices, alone or in combination, consistent with the

~~recommendations made by the Health Care Quality Improvement Committee and accepted by the Secretary of California Health and Human Services~~ *regulations adopted* pursuant to Section 128871 of the Health and Safety Code, for the program. This subdivision shall be implemented only if, and to the extent that, federal financial participation is available and is not jeopardized.

(c) A health care provider shall not bill a patient for care and services for which payment is denied by the program, including its participating health plans.

(d) The board may contract with a review organization that meets all applicable state and federal requirements, including Sections 1320c-1 and 1320c-3 of Title 42 of the United States Code, in terms of composition and function, for the purposes of carrying out the~~ recommendations of the Health Care Quality Improvement Committee and accepted by the Secretary of California Health and Human Services~~ *regulations adopted* pursuant to Section 128871 of the Health and Safety Code, for the Healthy Families Program and to the extent feasible, for all other programs administered by the board.

SEC. 11. Section 12739.5 is added to the Insurance Code, to read:

12739.5. (a) For the purposes of this part, "health care provider" means a health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250 of the Health and Safety Code, and a surgical clinic licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code.

(b) The board shall implement nonbilling or nonpayment policies and practices, alone or in combination, consistent with the ~~recommendations made by the Health Care Quality Improvement Committee and accepted by the Secretary of California Health and Human Services~~ *regulations adopted* pursuant to Section 128871 of the Health and Safety Code, for the program.

(c) A health care provider shall not bill a patient for care and services for which payment is denied by the program, including its participating health plans.

(d) The board may contract with a review organization that meets all applicable state and federal requirements, including Sections 1320c-1 and 1320c-3 of Title 42 of the United States Code, in terms of composition and function, for the purposes of carrying out the recommendations of the Health Care Quality

Improvement Committee and accepted by the Secretary of California Health and Human Services pursuant to Section 128871 of the Health and Safety Code, for the Healthy Families Program and to the extent feasible, for all other programs administered by the board.

SEC. 12. Article 5.4 (commencing with Section 14182) is added to Chapter 7 of Part 3 of Division 9 of the ~~Insurance~~*Welfare and Institutions* Code, to read:

Article 5.4. Adverse Events

14182. (a) The department shall implement the nonbilling and nonpayment policies and practices ~~recommended by the Health Care Quality Improvement Committee and accepted by the Secretary of California Health and Human Services~~ *adopted by regulations* pursuant to Section 128871 of the Health and Safety Code, for the fee-for-service Medi-Cal program, and to the extent feasible, for all other programs administered by the department. Medi-Cal managed care plans contracting with the department pursuant to Chapter 7 (commencing with Section 14000), Chapter 8 (commencing with Section 14200), or Chapter 8.75 (commencing with Section 14590) of Part 3 of Division 9, shall be required to implement similar nonbilling and nonpayment policies and practices through their contracts with health care providers.

(b) A health care provider shall not bill a patient for care and services for which payment is denied by the Medi-Cal program or any other program administered by the department pursuant to this article.

(c) Notwithstanding any other provision of law, and subject to applicable federal requirements, a health care provider shall exclude its costs related to adverse events subject to the nonbilling and nonpayment policies implemented pursuant to subdivision (a) from both of the following:

(1) The Annual Disclosure Report submitted by the health care provider to the Office of Statewide Health Planning and Development and which is used in the calculation of payment adjustments under the Disproportionate Share Hospital Program pursuant to Article 5.2 (commencing with Section 14166).

(2) The Medi-Cal 2552-96 cost report, and any other data, submitted by the health care provider to the department and which

is used for claiming reimbursement from the Safety Net Care Pool pursuant to Article 5.2 (commencing with Section 14166).

(d) This section shall be implemented only if, and to the extent that, federal financial participation is available and is not jeopardized for programs receiving federal funds.

(e) The department may contract with a review organization that meets all applicable state and federal requirements, including Sections 1320c-1 and 1320c-3 of Title 42 of the United States Code, in terms of composition and function, for the purposes of carrying out the ~~recommendations of the Health Care Quality Improvement Committee and accepted by the Secretary of California Health and Human Services~~ *regulations adopted* pursuant to Section 128871 of the Health and Safety Code, for the Medi-Cal program and to the extent feasible, for all other programs administered by the department.

(f) For the purposes of this article, "health care provider" means a health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250 of the Health and Safety Code, and a surgical clinic licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code.

SEC. 13. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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